Appendix C
HMPTS QA Policy Implementation Assessment

1.0 Overview

As described in Section 5.0 (Responsibility and Authority) of this document, the Associate Director of Plant Operations has primary responsibility for the achievement of the mission of the HMPTS Committee and is responsible for the quality of this work. The Associate Director of Plant Operations has delegated day-to-day responsibility for this QAP to the HMPTS Committee Chairperson, but maintains overall line responsibility for the QAP in Plant Operations. This appendix describes the process by which QA Policy is generated in Plant Operations HMPTS Committee and the organizational levels at which QA policy is made. It also describes the two phases by which the Directorate assesses the adequacy of QA policy implementation.

2.0 QA Policy Making Process

Because the quality assurance function is carried out by line management, the primary mechanism for developing QA policy is the consensus building process. By utilizing the consensus process to help define QA policy content, the HMPTS Committee strives to comply with the requirements issued by DOE and at the same time define QA policies that are value-added management tools that improve the overall performance of activities. Involving line management in the development of QA policy is especially important since they (as the customers of the policies) will be called upon to implement them in their activities.

3.0 QA Policy Levels

3.1 Level 1 (Directorate Requirement)

Level 1 QA policies are issued by the LLNL Director and their content is not formulated through the consensus process described above. For example, Sections 1.0 through 4.0 of this document (HMPTS QAP) are Level 1 QA policies. Implementation of Level 1 QA policies is a required part of the quality assurance function for all Laboratory employees.

3.2 Level 2 (Associate Directorate Approval)

Level 2 QA policy content is developed through the consensus process described above, but becomes a required part of the quality assurance function for all Plant Operations personnel upon approval and issuance by the Associate Directorate. For example, Section 5 of the HMPTS Plan and Procedure QP 1.1 SQAP Implementation guidelines are Level 2 policy.

3.3 Level 3 (HMPTS QA Guidance)

Level 3 QA guidance is applicable only to the activities of HMPTS members. For example, Specific Quality Assurance Plan and Implementation Guidance (SQAP Guidance) Procedure is a Level 3 QA policy. Guidance developed by the HMPTS Committee can become Level 2 QA policy if it is deemed appropriate by the Associate Director and formally issued as a revision or appendix to the QAP.

4.0 QA Policy Implementation Assessment

It is line management's responsibility to implement the QA Policy in their area of responsibility. The items below describe the methods by which Senior Management will assess the adequacy of the implementation of these policies throughout the HMPTS Committee and it's members operations.

Line management should strive to implement the QA policies in a way that complies with the policies and at the same time defines management controls that are value-added when they are applied to the overall performance of their activities. Management controls are value-added when they are applied using a graded approach based on the scale of cost, complexity, hazards, and programmatic significance of the work defined by the HMPTS Hazard/Assurance Prioritization System in Appendix B.

4.1 Policy Boundaries and Defining SQAP Management Controls

While the SQAP Guidelines found in Procedure QP 1.1 define the policy boundaries and minimum information that must be included in a SQAP, they do not specify the exact types of management controls that should be developed when implementing the 10 HMPTS QA Criteria. Defining the exact content of these management systems is a crucial component of management's responsibility to carry out their line management function. It is also consistent with the Associate Director's requirements that HMPTS personnel be empowered to perform their responsibilities (see Section 5.0, Criterion 3 Quality Improvement).

4.2 HMPTS Committee Members Management Assessment of QA Policy Implementation (Criterion 9)

Management assesses the adequacy of QA policy implementation in two ways: 1) the review and approval of SQAPs which are submitted, and 2) assessments of the actual implementation of the SQAPs in the day-to-day activities of an organization.

- The Committee Chairperson has delegated the responsibility for defining which personnel have review and approval authority for SQAPs to division heads. (See SQAP Guidance Procedure QP 1.1 for details).

- The review and approval process should be an iterative consensus process between those who generate the SQAPs and those who approve them, with the goal of coming to agreement on the adequacy of QA policy implementation.

- The primary criteria for evaluating the adequacy of the management controls defined in a SQAP is whether they will enable the organization or activity to meet its performance objectives within compliance to ES&H requirements and other Laboratory policies. Consequently, the emphasis is on the substance of the management systems within the boundaries established in the SQAP Guidelines, not upon the uniformity of SQAP format.

- The approval signatures on a SQAP signify that those who approved the SQAP believe the management systems described are adequate implementations and interpretations of the Level 1 and Level 2 QA policies. Disagreements that arise between the implementing organization and the Committee as a result of assessments performed by line management or independent assessments will be resolved by the Chairperson.

4.3 Independent Assessment of QA Policy Implementation (Criterion 10)

The HMPTS Committee Chairperson assesses the day-to-day implementation of SQAPs through the mechanism of CMO assessments. This process is described in HMPTS QAP, Section 5.0 (QA Criterion 10) and Appendix I (Independent Assessment Implementation Policy MOU) of this document.